



Practitioner's Docket No. 1779-8

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____
Inventor(s)

for _____
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: GALLOWAY, Edward L.

Application No.: 10 /628,199 Group No.: 3731

Filed: July 28, 2003 Examiner:

For: LOAD-CONTROLLED AUTO-ACTUATED SKIN INCISION DEVICE

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
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(Information Disclosure Statement [6-1]—page 1 of _____)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections
and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☒ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

- ☐ Exception(s) to above:
 - ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
 - ☐ Cumulative patents or publications identified in Section 5.

Section 9. Concise Explanation of English Language Listed Information Items (OPTIONAL)

NOTE: *"Applicants may, if they wish, provide a concise explanation of why English-language information is being submitted and how it is understood to be relevant. Concise explanations are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more are highly relevant to patentability." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

U.S. Patent No. 6,221,089, issued on April 24, 2001 to Mawhirt, teaches a device for making an incision in skin, having a housing with a slotted opening, and a triggering mechanism disposed within the housing for propelling a blade coupled thereto, through the slotted opening of the housing to make an incision in the skin.

U.S. Patent No. 5,851,215, issued on December 22, 1998 to Mawhirt et al., describes a low-cost safety lancet device for creating a skin incision. The lancet contains a unitarily formed plastic body, thereby making the lancet device easy to manufacture at a low cost. The lancet device includes a blade beam having a cutting blade disposed at one end for generating an incision in a patient's skin.

U.S. Patent No. 5,797,940, issued on August 25, 1998 to Mawhirt et al., discloses a device for making an adjustably sized incision in skin. The device comprises a housing having a slotted opening; a blade disposed within the housing for making an incision in skin; a blade triggering mechanism disposed within the housing, for propelling the blade through the slotted opening of the housing a given distance to make an incision of a predetermined size in the skin.

U.S. Patent No. 5,584,846, issued on December 17, 1996 to Mawhirt et al., teaches a low cost lancet device for creating a skin incision. The lancet contains a unistructurally formed plastic body, thereby making the lancet device easy to manufacture at low cost. The plastic body contains a resilient spring loop that attaches an arm element to an opposing base element. The spring loop is curved; therefore, the arm element is retained above the base element by the spring loop. A blade is disposed on the arm element.

U.S. Patent No. 5,529,581, issued on June 25, 1996 to Cusack, teaches a lancet device

and associated method used for obtaining a blood sample from a patient. The lancet includes a safety housing adapted to be placed against some area of the patient's skin, such as a finger. A slotted aperture is formed through the safety housing in the region of the housing to be placed against the skin.

U.S. Patent No. 5,527,333, issued on June 18, 1996 to Nikkels et al., teaches a disposable blood sampling device for slicing a precise incision of predetermined length and depth in the skin of a patient. The device includes a hollow housing having a bottom surface with an elongated slot adapted to contact the skin of the patient. A trigger is slidably disposed in the opening in the top surface of the housing. A single spring, only, is mounted in the housing in a relaxed condition when the device is not actuated. The spring is extended by the trigger when the device is actuated. A cutting blade is coupled to one end of the spring and extends through the elongated slot in the bottom surface of the housing to incise the skin of the patient when the device is actuated.

U.S. Patent No. 5,395,388, issued on March 7, 1995 to Schraga, discloses a single-use disposable lancet device including a housing wherein a spring is contained, the spring including a first end fixed within the housing and having a movable second end zone with a pointed blade or terminal end, the second end zone being movable relative to a normal position with the pointed terminal end contained within the housing and adjacent a first opening in the housing, between a cocked position completely within the housing and a piercing position with the pointed end momentarily exterior of the housing.

U.S. Patent No. 5,314,441, issued on May 24, 1994 to Cusack et al., describes a lancet device that uses a planar blade that implements an incision in the skin of a patient using a slicing action. There is a blade support arm pivotably secured within a hollow housing. The blade is

caused to reciprocate within the housing as it rotates with the blade support arm, wherein the blade exits the housing, implements an incision and is again retracted into the housing traversing a “tear drop” shaped path.

U.S. Patent No. 4,643,189, issued on February 17, 1987 to Mintz, discloses an apparatus for implementing a standardized skin incision which apparatus includes a housing having a base containing an elongated slot. The housing has an internal hollow which contains a movable pivot arm having a first pivotal end and a second end having a cam follower. Located within the housing is a cam surface upon which the cam follower of the pivot arm rides. The pivot end of the arm contains a cutting edge and is coupled to the housing such that it is enabled to move transversely while pivoting. The device produces a standard incision of a given length and a given depth as controlled by the reciprocating pivot arm and the cam surface.

U.S. Patent No. 4,535,769, issued on August 20, 1985 to Burns, describes an automatic retractable lancet assembly that includes a housing with a sharp-pointed lancet movable mounted therein. A depressible plunger and slide mechanism actuates the movement of the lancet outwardly from the housing. After this outward movement is completed, the actuator elements become dissociated from further movement of the lancet. Subsequently, the lancet is automatically retracted back inside the housing by a spring element.

U.S. Patent No. 4,064,871, issued on December 27, 1977 to Reno, teaches a device for making a standardized reproducible blade incision in a human or animal subject for clinically testing the bleeding time of the subject. The device comprises a housing having a surface with a slot defining a longitudinal opening into the housing. A blade is mounted within the housing for movement of the blade tip through and along the slot.

**Section 1 . Identification of Person() Making This Information
Disc l sure Statement**

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
☒ in the practitioner's file.

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SIGNATURE OF PRACTITIONER

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